

20. An implantable medical device comprising a substrate element fabricated of at least one of a shape memory and superelastic material, at least one transition point of the substrate element being capable of being induced by at least one of an endogenous energy stimulus selected from the group consisting of fluid pressure, fluid shear forces, body temperature, cellular binding and molecular binding, and exogenous energy stimulus selected from the group consisting of temperature, pressure, microwave, ultrasound, RF, ultraviolet, infrared, magnetic resonance, x-rays, beta and gamma irradiation.

### Remarks

The pending claims were restricted into the following groups of inventions:

Species I represented by Figs. 1-4;

Species II represented by Figs. 5-7; and

Species III represented by Figs. 8-10.

The Applicants understand Species I (Figs. 1-4) to be drawn to an implantable medical device comprising sensor members that are comprised of a plurality of cantilever members as claimed by Claims 1-19. Species II (Figs. 5-7) is drawn to an implantable medical device comprising a plurality of integral sensor regions as claimed by Claim 20. Species III (Figs. 8-10) is drawn to an implantable medical device comprising a biosensor for sensing endothelialization as claimed by 20.

### ***Provisional Election with Traverse***

Applicants provisionally elect to prosecute the claim of Species Group II, i.e., Claim 20 with traverse. Applicants respectfully submit that, while there may be no unifying generic claim originally presented, the originally presented Claims 1-20 present no undue burden on the Examiner in searching the claimed inventions represented by the three groups that the Patent Office. The originally presented Claim 1-20, and new Claims 21-22 are all directed to an "implantable medical device" and, as such, all fall within U.S. Class 623 entitled "PROSTHESIS (I.E., ARTIFICIAL BODY MEMBERS), PARTS

THEREOF, OR AIDS AND ACCESSORIES THEREFO.” Because the pending claims all include a type of a reactive sensor element, i.e., “sensor member” in Claims 1-19 and the “transition point of the substrate element” in Claim 20, there appear to be only a limited number applicable sub-classes under Class 623 in which the Examiner must search, i.e., Sub-classes 1.18, 1.19, 1.2, 1.3, 11.11, 23.64, 23.7, 23.71, 243, 25 and 66.1. Thus, searching this class and these sub-classes will for either of the identified Species I, II or III, will likely yield the same search results for each alleged Species.

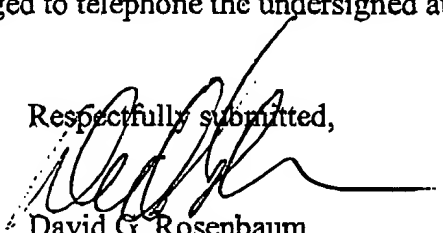
***Summary of Preliminary Amendment***

New Claim 21 is presented as a generic claim covering all three of the Examiner’s identified Species. New Claim 22 is a species claim within the elected Species II.

This Preliminary Amendment and Response to Restriction Requirement is being timely filed along with a three-month extension of time along with the appropriate fee.

Should the Examiner require any further information or wish to discuss an aspect of this Response, the Examiner is encouraged to telephone the undersigned at the telephone number set forth below.

Respectfully submitted,

  
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## VERSION WITH MARKINGS SHOWING CHANGES

1. The implantable medical device according to Claim 22, wherein, the sensor member is fabricated from at least one of a shape memory or a superelastic material coupled to the implantable substrate carrier.
2. The implantable medical device according to Claim 1, wherein the implantable substrate carrier is fabricated of a biocompatible material selected from the group of stainless steel, tantalum, gold, platinum, titanium, nickel, vanadium metal alloys thereof, nickel-titanium, elgiloy and combinations thereof.
3. The implantable medical device according to Claim 1, wherein the implantable substrate carrier consists essentially of a metal alloy.
4. The implantable medical device according to Claim 1, wherein the implantable substrate carrier consists essentially of a nickel-titanium alloy.
5. The implantable medical device according to Claim 2, wherein the sensor member consists essentially of a metal alloy.
6. The implantable medical device according to Claim 4, wherein the sensor member consists essentially of a nickel-titanium alloy.
7. The implantable medical device according to Claim 1, wherein the sensor member further comprises a plurality of cantilever members.
8. The implantable medical device according to Claim 7, wherein the plurality of cantilever members are fabricated of at least one of a shape memory material, a superelastic material, an elastically deformable material or a plastically deformable material.



9. The implantable medical device according to Claim 8, wherein the plurality of cantilever members have binary functionality having a first "off" position and a second "on" position.

10. The implantable medical device according to Claim 7, wherein the plurality of cantilever members are configured to have electromechanical response curves which shift upon a quantum of applied energy thereto.

11. The implantable medical device according to Claim 1, wherein the sensor member further comprises structural elements of the substrate carrier that are capable of altering a conformation of the implantable substrate carrier upon martensitic transformation of the at least one of a shape memory or a superelastic material.

12. The implantable medical device according to claim 22, wherein the sensor member comprises a plurality of sensor regions integrally defined on at least one of a luminal or abluminal surface of the endoluminal prosthesis.

13. The implantable medical device according to Claim 12, wherein the endoluminal prosthesis is selected from the group consisting of stents, stent-grafts, grafts, valves, filters and occluders.

14. The implantable medical device according to Claim 12, wherein the endoluminal prosthesis and the at least one of a plurality of sensor regions further comprise a metal alloy selected from the group consisting of shape memory metal alloys, superelastic metal alloys, elastically deformable metals or plastically deformable metals.

15. The implantable medical device according to Claim 14, wherein the endoluminal prosthesis further comprises of a nickel-titanium alloy.

16. The implantable medical device according to Claim 14, wherein the at least one of a plurality of sensor regions further comprises a nickel-titanium alloy.

17. The implantable medical device according to Claim 14, wherein the at least one of a plurality of sensor regions further have a transition point different than a transition point of the endoluminal prosthesis.

18. The implantable medical device according to Claim 14, wherein the endoluminal prosthesis further comprises a plurality of wall elements, each of the plurality of wall elements further comprised of at least one shape memory or superelastic material, at least some of the plurality of wall elements being comprised of a first shape memory or superelastic material having a first transition point  $T_1$  and at least some of the plurality of wall elements being comprised of a second shape memory or superelastic material having a second transition point  $T_2$ , wherein  $T_2$  is greater than  $T_1$ .

19. The implantable medical device according to Claim 14, wherein the endoluminal prosthesis further comprises a plurality of wall elements; each of the wall elements being comprised of a laminate of at least two shape memory or superelastic materials, a first shape memory or superelastic material having a first transition point  $T_1$  and a second shape memory or superelastic material having a second transition point  $T_2$ , wherein  $T_2$  is greater than  $T_1$ .

20. An implantable medical device comprising a substrate element fabricated of at least one of a shape memory and superelastic material, at least one transition point of the substrate element being capable of being induced by at least one of an endogenous energy stimulus selected from the group consisting of fluid pressure, fluid shear forces, body temperature, cellular binding and molecular binding, and exogenous energy stimulus selected from the group consisting of temperature, pressure, microwave, ultrasound, RF, ultraviolet, infrared, magnetic resonance, x-rays, beta and gamma irradiation.

21. An implantable medical device capable of interacting with and reacting to physiological stimulus comprising a substrate carrier element.

22. The implantable medical device according to Claim 21, further comprising  
ne a sensor member that interacts with one of a number of physiological stimulus and  
translates the stimulus to effect a physical change in the implantable medical device.